## REMARKS

Applicant respectfully requests further examination and reconsideration in view of the arguments set forth fully below. In the Office Action mailed July 5, 2006, claims 1-20 have been rejected. In response, the Applicant has submitted the following remarks amended claims 1, 3, 5, 7, 9, 12, 18 and 20, and cancelled claims 2, 4, 6, 8, 11 and 16. Accordingly, claims 1, 3, 5, 7, 9-10, 12-15 and 17-20 are pending. Favorable reconsideration is respectfully requested in view of the amended claims and the remarks below.

### *Rejections Under 35 U.S.C. §102*

Claims 1-2, and 5-17 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Application Publication No. 2004/0230456 to Lozier et al (hereinafter Lozier). The Applicant respectfully disagrees with this rejection.

Lozier teaches a software system for identifying patients that may be appropriate candidates for implantation with an implantable cardioverter/defibrillator. Lozier does not teach an ACE system configured to compare a set of patient data to stored patterns to determine a measurement with an analysis module, nor further configured to compare the measurement to determine a correlation with a decision support module, wherein the correlation reflects a level of heart disease, and further a diagnosis module configured to diagnose a sudden cardiac death risk score based on the level of heart disease. Furthermore, Lozier does not teach a method of displaying a prediction of sudden cardiac death comprising generating a single report based on data acquired from a plurality of medical devices, wherein the single report includes image data, image pattern, image correlation, image measurement, mathematical measurement, parameter value, and a range. Lozier also does not teach a single report including a recommended treatment and a recommended follow up test.

In contrast to the teachings of Lozier, the system and method of the present invention includes a set of data acquisition devices capable of collecting patient data

including ECG and image data, and a set of analysis modules configured to determine a mathematical measurement, an ECG measurement and an image measurement, wherein a decision support module receives these measurements and determines a level of heart disease in the patient. A diagnosis module then calculates an SCD score based on the level of heart disease. Furthermore, the method and system of the present invention includes a single report based on data acquired from the data acquisition devices, such that the single report includes patient identifiers, patient history, physician identifiers, ECG data, ECG patterns, ECG correlation, ECG measurement, image data, image patterns, image correlations, image measurements, mathematical measurements, parameter values, ranges, SCD risk score, diagnosis, recommended treatments, and recommended follow up tests.

Claim 1 is directed to a method of predicting sudden cardiac death in a patient, the method comprises acquiring patient data from a plurality of medical equipment databases with a set of acquisition devices, comparing the patient data to stored patterns to determine a measurement with an analysis module, comparing the measurement to a range to determine a correlation with a decision support module, wherein the correlation reflects a level of heart disease, and diagnosing a sudden cardiac death risk score with a diagnosis module. As described above, Lozier does not teach comparing patient data to determine a measurement and further comparing the measurement to a range to determine a correlation. For at lease these reasons, the independent claim 1 is allowable over the teachings of Shapland.

Claims 2 and 5-10 are dependent upon the independent claim 1. As discussed above, the independent claim 1 is allowable over the teachings of Lozier. Accordingly, claims 2, 5, 7, 9 and 10 are also allowable as being dependent upon an allowable base claim. Claims 6 and 8 have been cancelled.

Claim 11 has been cancelled.

Claim 12 is directed to a computer program embodied by a computer readable medium capable of being executed by a computer, the computer program for use in a sudden cardiac death predication system comprising an acquisition module that communicates over a network to acquire patient data from a plurality of medical equipment databases, an analysis module that analyzes the patient data and calculates a plurality of measurements, a decision support module that analyzes the plurality of measurements and determines a level of heart disease, a diagnosis module that provides a medical diagnosis and sudden cardiac death prediction score based on the level of heart disease, and a report module that provides a single report including at least the sudden cardiac death prediction score. As discussed above, Lozier does not teach the analysis module, the decision support module, nor the diagnosis module as taught and claimed in the present invention. For at least these reasons, the independent claim 12 is allowable over the teachings of Lozier.

Claims 13-16 are dependent upon the independent claim 12. As discussed above, the independent claim 12 is allowable over the teachings of Lozier. Accordingly, claims 13-16 are also allowable as being dependent upon an allowable base claim.

Claim 17 is directed to a method of displaying a prediction of sudden cardiac death, the method comprising generating a single report based on data acquired from a plurality of medical devices, the single report including at least one of a patient history and a physician identifier, the single report including at least one of electrocardiogram data, an electrocardiogram pattern, an electrocardiogram correlation, an electrocardiogram measurement, image data, an image pattern, an image correlation, an image measurement, a mathematical measurement, a parameter value, and a range, and the single report including at least one of a sudden cardiac death risk score, a diagnosis, a recommended treatment, and a recommended follow-up test, and displaying the single report for review by medical personnel. As discussed above, Lozier does not teach a single report including image data, image patterns, image correlations, image measurements, mathematical measurements, parameter values, ranges, recommended

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treatments, nor a recommended follow up test. For at least these reasons, the independent claim 17 is allowable over the teachings of Lozier.

## *Rejections Under 35 U.S.C. §103*

Claims 3-4 and 8-20 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Lozier in view of U.S. Patent No. 6,370,423 to Guerrero et al. (hereinafter Guerrero). The Applicant respectfully disagrees with this rejection.

Guerrero teaches a method of analyzing biological signals representative of voltages changes, including obtaining an analog biological signal representative of voltage changes, using digital processing software to digitize the biological signal, displaying the process biological signal in analog form on the display in a time compressed format, wherein an amount of compression for the time compressed format is selected such that graphical patterns are made perceivable on the display that signify an abnormality in the biological signal, and visually analyzing the biological signal under the display to characterize the abnormality (Guerrero, abstract). However, Guerrero does not teach a decision support module nor a diagnosis module configured to generate a single report based on data acquired from a plurality of medical devices, wherein the single report includes image data, image pattern, image correlation, image measurement, mathematical measurement, parameter value, and a range. Guerrero also does not teach a single report including a recommended treatment and a recommended follow up test.

Claim 3 depends upon the independent claim 1. As discussed above, the independent claim is allowable over the teachings of Lozier. For at least these reasons, claim 3 is allowable as being dependent upon an allowable base claim. Claim 4 has been cancelled.

Claims 18 and 20 are directed to a system and a medical device for determining a risk or predicting sudden cardiac death, and these claims include calculating a sudden cardiac death risk score based on patient data. For the same reasons as indicated in the

argument for claims 1 and 12, claims 18 and 20 are allowable over Lozier and Gurerro. Claim 19 has been cancelled.

For these reasons, Applicant respectfully submits that all of the claims are now in a condition for allowance, and allowance at an early date would be appreciated. Should the Examiner have any questions or comments, they are encouraged to call the undersigned at 414-271-7590 to discuss the same so that any outstanding issues can be expeditiously resolved.

Respectfully submitted,

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